K001238

MAY - 3 2000

Summary of Safety and Effectiveness

Device Modification Name: Lorenz Titanium Fracture / Reconstruction Plating System

Predicate 510(k): Wuerzburg Titanium Bone Plate and Bone Screw System, K854886

Additional Substantial Equivalence: The Lorenz Titanium Fracture / Reconstruction Plating System is equivalent to many competitive systems including KLS-Martin Mandibular Fracture/Reconstruction System, K950045.

Intended Use: The Lorenz Titanium Fracture / Reconstruction Plating System is intended for use in the stabilization and fixation of mandibular fractures and mandibular reconstructive surgical procedures

Contraindications

- Active infection.
- Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation.
- Patients with limited blood supply, insufficient quantity or quality of bone, or latent infection.
- Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.

Device Modification Description: Modifications to the fracture / reconstruction systems are not functionally significant and would typically be considered a letter to the file for the predicate 510(k). The newest design for this type of plate is for the fracture plates. The plates were typically double compression plates and now have single compression features. These plates have a slight neck or narrowing between the holes. These plates are the same thickness and do not represent a major modification to the system. The fracture / reconstruction plate designs are the same basic shapes and sizes as competitive devices for fracture and reconstructive procedures. This special 510(k) is being filed to be certain that the plates listed have a current 510(k) which clearly covers the precise indications.

Sterility Information:
The plates and screws will be marketed as non-sterile, single use devices.

Potential Risks: The following is a listing of potential risks, which will be included in the package insert.

- Nonunion or delayed union which may lead to breakage of the implant
- Bending or fracture of the implant
- Loosening of the implant
- Metal sensitivities or allergic reaction
- Decrease in bone density due to stress shielding
- Pain, discomfort, or abnormal sensations due to the presence of the device
- Nerve damage due to surgical trauma
- Necrosis of bone

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 3 2000

Ms. Diana Preston
Walter Lorenz Surgical, Incorporated
1520 Tradeport Drive
Jacksonville, Florida 32218

Re: K001238
Trade Name: Lorenz Titanium Fracture/Reconstruction Plating System
Regulatory Class: II
Product Code: JEY
Dated: April 14, 2000
Received: April 18, 2000

Dear Ms. Preston:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): ~~unknown~~ K001238

Device Name: Lorenz Titanium Fracture / Reconstruction Plating System

Indications For Use: The Lorenz Titanium Fracture / Reconstruction Plating System is intended for use in the stabilization and fixation of mandibular fractures and mandibular reconstructive surgical procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Randy Shue, DMD, MPH for MSR

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K001238

Prescription Use ✓ OR Over-The-Counter Use___
(Per 21 CFR 801.109)